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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,269	01/27/2004	Debra Ann Merrill	0470-040032	7572

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EXAMINER	
LILLING, HERBERT J	

ART UNIT	PAPER NUMBER
1657	

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08/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/765,269	MERRILL ET AL.	
	Examiner	Art Unit	
	HERBERT J. LILLING	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-36* is/are pending in the application.

4a) Of the above claim(s) *17-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *17-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Receipt is acknowledged of a request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 06, 2007 has been entered.

2. Claims 17-36 remain pending in this application.

Claims 1-16 were previously cancelled.

Claims 17-32 remain withdrawn as directed to nonelected invention(s).

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 33-36 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the product as claimed based on the processes steps in the specification that clearly contains sufficient process steps that provides enabling support for the gluten-free peptide preparation but the claimed preparation lacks sufficient and reasonable properties for the claimed peptide preparation. Therefore, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and practice the invention commensurate in scope with these claims. The search and examination must

be commensurate in scope with the claimed product, which requires the structure as well as the components within the scope of the "peptide preparation".

Applicant has failed to be in full compliance with the first paragraph under 35 U.S.C. 112..

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 33-36 stand rejected under 35 U.S.C. 102(e) as anticipated by

Auriol et al U.S. 5,554,508 for the same grounds as submitted in the prior office action as recited:

> "Auriol et al teaches a hydrolysate of wheat by enzymatically hydrolyzing the wheat with a protease at a neutral or alkaline pH.
>
> Auriol et al is considered to produce a product from the hydrolysis of wheat gluten with an enzyme (Alcalase) at an alkaline pH within the scope of the claimed inventions
>
> > Example 2: Alcoholysis of Wheat Gluten Peptides
> > The wheat gluten peptides were prepared by hydrolyzing gluten with subtilisin (Alcalase) at pH=8: the average molar mass of the water-

> soluble peptides determined according to the conditions described in Example 1 is 4200.

The product(s) obtained by the above reference is considered to be within the scope of the inventions in view of the following decisions:

> It is well settled that if a reference reasonably teaches a product which is identical or substantially identical or are produce by identical or substantially identical process, the PTO can require an applicant to prove that the prior art products do not inherently possess the characteristics of his claimed product. A rationale given for shifting the burden of going forward to applicant is that the PTO does not possess the facilities to manufacture or to obtain and compare prior art products, see **In re Brown**, 459 F.2d 531, 535,173 USPQ 685, 688 (CCPA 1972); **In re Best**, 562 F.2d 1252, 1255,195 USPQ 430, 433-434 (CCPA 1977)."

The Declaration has been found to be fatally defective since Applicant has failed to provide a direct comparison between Example 3 with the scope of any of the examples or a showing that the product of the reference does not produce a wheat gluten that contains less than 200 ppm of gliadin. The reference, Auriol et al, US 5,554,508, clearly teaches that the process is drawn to the preparation of wheat gluten in which the ingredients of the wheat gluten are esterified by alcoholysis as provided by Example 3 employing the same enzyme and having similar conditions as required by the instant claims. It is presumed that the esterified peptide composition of Auriol et al which contains the additional step of Alcoholysis, not excluded by the instantly claimed invention, meets the condition of obtaining a composition having less than 200 ppm of

free gliadin. Applicant has failed to provide any direct comparison or any facts as to the differences due to the additional step of Alcoholysis. Examiner will consider any further declaration or any amendment(s), which will patentably distinguish between the two compositions between the prior art composition of Auriol et al and that of the instant claims.

5. In accordance with this Tech Center Policy based on above restriction containing product claims and process claims, this Examiner will rejoin any non-elected process claims upon the election of a product claim which is subsequently is found allowable in view of the following guidelines:

F.P.: Ochiai/Brouwer Rejoinder form paragraph

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejections are governed by 37 CFR 1.116; amendments submitted after allowances are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims

and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. **No claim is allowed.**

7. This is a Continuation of applicant's instant Application. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. It is noted that the limitation added to independent claim 33 has already been considered in the prior final rejection as noted by claim 34. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is **571-273-8300**. or SPE Jon Weber whose telephone number is 571-272-0925. Examiner can be reached Monday-Friday from about 7:30 A.M. to about 7:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

H.J.Lilling: HJL
(571) 272-0918
Art Unit **1657**
August 27, 2007

Dr. Herbert J. Lilling
Primary Examiner
Group 1600 Art Unit 1657